

<b>Examiner-Initiated Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/483,337	KOOL, ERIC T.	
	<b>Examiner</b>	<b>Art Unit</b>	
	L. E. Crane	1623	

**All Participants:**

(1) L. E. Crane.

(2) Victoria Sandberg.

**Status of Application:** Non-final Rejection

(3) Michael Woodward.

(4) \_\_\_\_\_.

**Date of Interview:** 8 July 2005

**Time:** \_\_\_\_\_

**Type of Interview:**

- ☒ Telephonic  
☐ Video Conference  
☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

**Exhibit Shown or Demonstrated:** ☐ Yes ☒ No

If Yes, provide a brief description:

**Part I.**

**Rejection(s) discussed:**

*all remaining of record*

**Claims discussed:**

*all of record*

**Prior art documents discussed:**

*None specifically*

**Part II.**

**SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:**

*See Continuation Sheet*

**Part III.**

- ☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.  
☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

  
 (Examiner/SPE Signature)

\_\_\_\_\_  
 (Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed: During preparations for the interview including careful review of the case, examiner reached the following three conclusions. The only allowable subject matter which was readily apparent to examiner was the claimed process specifically limited to phosphoroselenoate and phosphorotelluroate compounds in "directly adjacent" ligating probes and with oligonucleotide probes of 7 units or longer. Other allowable limitations may include the presence or absence of a single nearby mismatch. The phosphoroselenoate limitation may be allowable over the Gryaznov reference (PTO-1449 ref. AB) because Gryaznov i) did not disclose a "phosphoroselenoate" probe as a reactant in any examples and ii) Gryaznov did all couplings with a different 5'-modification on the other probe equipped with a chemically sticky end. (NB: Amendments to the claims distinguishing over this prior art would be required prior to a finding of allowability.) Claims which require ligation in the presence of with a gap of 1 or two nucleotide units or an overlap of 1 or two nucleotide units are not allowable because there is no showing in the disclosure or a showing in a declaration under 37 C.F.R. §1.132 that "loops" can be generated in the vicinity of the ligation site in either the "gap" or the "overlap" situations.

In re the claims which claim that probes with "less than 7 nucleotide units" can be effective in chemical autoligations, there are no exemplifications in support of these claims in the disclosure and no declarations providing additional data in support of processes relying on effective hybridizations with probes with lengths between 1 and 6 nucleotides. During the interview the following discussions occurred.

Objections to incorporation by reference were found to be inappropriate in the absence of a showing that a specific incorporation is likely to be inaccurate because the subject matter has not been specifically identified and in view of ongoing corrections is likely to change; for example a nucleic acid sequence identified only by a GenBank accession number, or a reference disclosing several methods of nucleic acid terminal modification has not been following by a clear indication of which particular method of modification is being relied on in the present specification.

Applicant alleged that the temperature is not critical citing Figure 15 as basis for this conclusion. Examiner Crane responded with the observation that there was no specific disclosures supporting the numerous processes being claimed and suggested 1.132 declarations including process details for each as appropriate. Examiner Crane noted in particular the following three situations wherein additional 1.132 declaration evidence would be particularly welcome:

- 1) autoligations wherein a "gap" must be bridged to achieve ligation (must produce a "lump" in the template chain of the product),
- 2) autoligations wherein an "overlap" exists prior to achieving ligation (must produce a "lump" in the ligated chain of the product), and
- 3) autoligations wherein probes with less than 7 base are hybridized prior to chemical ligation.

Examiner M. Woodward noted the distinction between an "opinion" declaration and a "facts" declaration, indicating that the USPTO expects the latter, and that the former would not be particularly helpful.

In the matter of identifying the autoligation products in the "two probe" claims, Examiner Crane suggested that the last line should include the possibility of -- no product --.

In the matter of three probe claims, Examiner Crane suggested that the possibility of a favored product (90:10) needed to be made clear (product or products) because this was a possibility in addition to an exclusive product.

Examiner Crane indicated that the case where Selenium analogues of phosphorothioates were present at the 3'-terminus was not known/exemplified in the prior art.

The term of art "comprising" is a two edged sword when the reaction site architecture is the issue, because this term makes it easier for the prior art to be applied in an art rejection. It was noted that this term raised the possibility, in the matter of 5'-leaving groups, that this term permitted the present claims to be seen as reading on Lehninger/Gryaznov wherein 5'-haloacetyl groups would be "included" as a possibility by the term "comprising a 5'-leaving group."

Alternatively, the substitution of narrower terms of art in the claims makes avoidance of the prior art more easily achieved.

During the discussion, it was noted that the term "mutant polymorphism" is a redundancy; i.e. a "mutant sequence" is also known as a "polymorphic sequence."

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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(2) Ms. Victoria A. Sandberg.
**Status of Application:** Non-final Rejection

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**Date of Interview:** 9 November 2005
**Time:** \_\_\_\_\_

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Exhibit Shown or Demonstrated: ☐ Yes ☒ No

If Yes, provide a brief description:

**Part I.**

Rejection(s) discussed:

None

Claims discussed:

56-60

Prior art documents discussed:

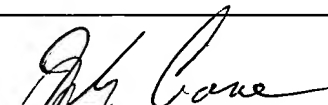
None

**Part II.**
**SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:**

*Applicant was advised that the FAXed proposed amendment received 11/09/2005 was acceptable. Applicant authorized an examiner's amendment and was advised that the case was now allowable and would be passed to issue in due course.*

**Part III.**

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